

REMARKS

Reconsideration of this application in light of the above amendments and following remarks is respectfully requested. Claims 1-18 are currently pending in this application.

Amendments

Claims 16-18 have been canceled.

Claim 1 has been amended to delete two disorders, namely neurological disorders and physical trauma disorders. It has been further amended to properly present the first Markush group.

Claim 7 has been amended to correct the dependency from claim 5 to claim 2.

New claim 19 is directed to a method for alleviating or protecting against the symptoms of a neurological medical disorder involving accelerated rates of apoptosis or necrosis in a mammalian body, namely Parkinson's disease, senile dementia and Alzheimer's disease. Support for this amendment may be found in originally filed claims 1 and 15.

Applicants submit that no new matter has been added by these amendments.

Claim Rejections

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-18 stand rejected under 35 U.S.C. §112, Second Paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 7 have been amended. Applicants believe that this rejection is now moot.

In particular, the Office Action required correction of the Markush language in Claim 1 and the dependency of Claim 7. As noted above, Claim 1 has been amended to correct the Markush language and Claim 7 has been amended to depend on Claim 2. Accordingly, it is submitted this rejection is now moot and Applicants respectfully request that it be withdrawn.

Rejection Under 35 U.S.C. §102(b)

Claims 1-10, 17 and 18 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Bolton, US Patent 5,591,457 ("457"). The Office Action states that '457 teaches the claimed method for a physical trauma disorder, namely, miscarriage and organ rejection. Claim 1 has been amended to delete the term "physical trauma disorder." Accordingly, Applicants submit that this rejection is now moot and respectfully request that it be withdrawn.

First Rejection Under 35 U.S.C. §102(e)

Claims 1-10 and 15 are rejected as allegedly anticipated by Bolton, US Patent 5,834,030 ("030"). The Office Action states that '030 teaches the claimed method for a neurological disorder. This rejection is respectfully traversed. Claim 15 has been canceled and new Claims 19-28 have been added. In light of the amendment to Claim 1 addition of Claims 19-28, this rejection is address with respect to new independent Claim 19.

New Claim 19 is directed to a process for alleviating or protecting against the symptoms of a neurological medical disorder involving accelerated rates of apoptosis or necrosis in a mammalian body, which process comprises selecting a patient having a

neurological medical disorder selected from the group consisting of Parkinson's disease, senile dementia and Alzheimer's disease and administering an aliquot of blood treated according to this invention. The '030 patent does not teach this claimed method.

At column 5, line 66 through column 6, line 2, the '030 patent teaches diseases that are illustrative of known conditions which are potentially treatable by the extracorporeal treatment of blood. The list of diseases includes neurological conditions such as depression; no other neurological disorders are taught. Specifically, there is no teaching in the '030 patent of the particular neurological conditions claimed, namely Parkinson's disease, senile dementia and Alzheimer's disease, which are very different from depression. Further, the '030 patent does not teach selecting a patient having such a disorder for treatment. Accordingly, it is submitted that the '030 patent does not anticipate the method of Claim 19 and withdrawal of this rejection is requested.

Second Rejection Under 35 U.S.C. §102(e)

Claims 1-10, 17 and 18 are rejected as allegedly anticipated by Tremblay et al., 6,136,308 ("'308"). The Office Action states that the '308 patent teaches the claimed method for a physical disorder. This rejection is respectfully traversed.

Claim 1 is now alleviating or protecting against the symptoms of a disorder, where the patient has, is suspected of having or will be exposed to radiation exposure disorders, chemical exposure and ingestion disorders. These disorders are very different from the stress disorders described in the '308 patent, which include those listed in column 6, lines 22-65, such as preconditioning against anginal episodes, unstable angina, organ transplant and transient ischemic attacks (TIAs). There is nothing taught in the '308 patent that

would lead one skilled in the art to consider that stress induced by exposure to radiation, chemical exposure or ingestion disorders could be treated according to the method taught by the '308 patent. The '308 patent does not teach or suggest that stress induced by exposure to radiation, chemical exposure or ingestion disorders are in any way related to anginal episodes, unstable angina, organ transplant and transient ischemic attacks (TIAs). Accordingly, Applicants submit that the '308 patent does not teach the claimed invention and respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 1-18 stand rejected as allegedly unpatentable over Bolton ('030) taken in combination with Bolton ('457) and Tremblay et al ('308). As noted above, Claims 1 and 7 have been amended and new Claims 19-28 have been added. For the following reasons, this rejection is respectfully traversed.

Initially, Applicants note that the test for non-obviousness articulated by the Court of Appeals for the Federal Circuit in *In re Vaeck* requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should practice the claimed methods; and (2) whether the prior art would also have provided a reasonable expectation of success to such a skilled artisan. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

This requirement goes to the question of motivation, and refers to a well established holding from earlier case law that there must be some logical reason at the time of the invention for combining the references along the lines of the invention; otherwise the use of

the teachings as evidence of non-obviousness will entail prohibited hindsight. *Ex parte Stauber and Eberle*, 208 U.S.P.Q. 945, 946 (Bd. App. 1980).

In a first aspect, the claimed invention relates to a process of alleviating or protecting against the symptoms of a medical disorder involving accelerated rates of apoptosis or necrosis in a mammalian body, wherein the disorder is selected from radiation exposure disorders, and chemical exposure and ingestion disorders. The process comprises reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs of the mammalian body by (a) reacting an aliquot of blood from the mammalian body *ex vivo* with at least one stressor selected from the group consisting of a temperature above or below body temperature, ultraviolet light and an oxidative environment and (b) administering the aliquot of blood treated in step (a) to the mammalian body.

In another aspect, the claimed invention is directed to treating a process of alleviating or protecting against the symptoms of a medical disorder involving accelerated rates of apoptosis or necrosis in a mammalian body, wherein the disorder is selected from Parkinson's disease, senile dementia and Alzheimer's disease, which process comprises reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs of the mammalian body. The process comprises reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs of the mammalian body by (a) reacting an aliquot of blood from the mammalian body *ex vivo* with at least one stressor selected from the group consisting of a temperature above or below body temperature, ultraviolet light and an oxidative environment and (b) administering the aliquot of blood treated in step (a) to the mammalian body.

As to the rejection under 35 U.S.C. §103(a), this rejection is in error because the cited references fail to teach or suggest the claimed invention. Further, the cited references fail to provide motivation to treat reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs of the mammalian body or any of the recited diseases, namely radiation exposure disorders, and chemical exposure and ingestion disorders (as in Claim 1), or Parkinson's's disease, senile dementia and Alzheimer's disease (as in Claim 19).

Specifically, as noted above, at column 5, line 66 through column 6, line 2, the Bolton '030 patent teaches diseases that are illustrative of known conditions which are potentially treatable by the extracorporeal treatment of blood. The list of diseases includes neurological conditions such as depression; no other neurological diseases are taught. There is no teaching in the '030 patent of the particular neurological conditions claimed, namely Parkinson's disease, senile dementia and Alzheimer's disease, nor does the '030 patent teach selecting such a patient for treatment. Further, one skilled in the art would not consider that depression and Parkinson's, senile dementia and Alzheimer's could be treated by the same methods. Accordingly, it is submitted that the '030 patent does not teach or suggest the method of Claim 1 or 19.

As also noted above, '308 teaches stress disorders which include those listed in column 6, lines 22-65, such as preconditioning against anginal episodes, unstable angina, organ transplant and transient ischemic attacks (TIAs). As discussed above, this reference does not teach or suggest the claimed invention, nor would one skilled in the art consider that radiation exposure, chemical exposure or ingestion disorders could be treated by the same method.

The '457 patent teaches treating a variety of diseases, such as arterial occlusive disease such as peripheral vascular disease; thrombotic disease such as coronary thrombosis, pulmonary thrombosis, arterial thrombosis, and venous thrombosis; circulatory disorders such as Raynaud's disease; stroke; pre-eclampsia; and hypertension. '457 does not teach or suggest treating any of the disease claimed in Claims 1 and 19. Again, one skilled in the art would not have considered that the claimed diseases could be treated by the same method as the diseases taught in '457.

The Office Action further states that the references teach "immune system" disorders and that the method is used to counteract the adverse effects of stress in a mammalian patient. It further states that since radiation exposure, chemical exposure and ingestion disorders are all related in that they effect the immune system in a negative way, they thereby create an immune system disorder, which method is taught by the cited references. It is submitted that this logic may be applied to any disease or disorder affecting a mammalian patient. One skilled in the art would not have considered that the claimed disease may be treated in the same manner as diseases taught by the cited references. Accordingly, none of the references, either alone or in combination teach or suggest the claimed invention.

For the reasons noted above, none of the references, either alone or in combination, teach or suggest the claimed method of treating radiation exposure disorders, and chemical exposure and ingestion disorders (as in Claim 1), or the claimed method of treating Parkinsons's disease, senile dementia and Alzheimer's disease (as in Claim 19). Applicants submit that this rejection is in error. Further, as noted above, one skilled in the art would not have considered that there would have been a reasonable expectation of success for

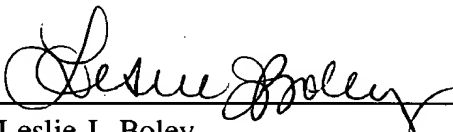
treating the claimed disorders based upon the teaching of any of '030, '308 or '457. The disorders of Claims 1 and 19 are significantly different from and are not related to those taught by any of the cited references; one skilled in the art would not have considered that the claimed diseases could be treated the same way as the diseases taught by the cited references. Accordingly, Applicants believe that this rejection is in error and respectfully request that it be withdrawn.

Conclusion

For the reasons noted above, Applicants respectfully request that all of the remaining rejections be removed and submit that application is now in order for allowance. Early notice to that effect is earnestly solicited.

Respectfully submitted,

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MARKED-UP CLAIMS SHOWING AMENDMENTS

1. (amended) A process of alleviating or protecting against the symptoms of a medical disorder involving accelerated rates of apoptosis or necrosis in a mammalian body, [said disorder being selected from radiation exposure disorders; chemical exposure and ingestion disorders; neurological disorders; and physical trauma disorders;] which process comprises [reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs of the mammalian body by] (a) selecting a patient having, suspected of having or will be exposed to conditions which cause a medical disorder selected from the group consisting of radiation exposure disorders; and chemical exposure and ingestion disorders; (b) reacting an aliquot of blood from the mammalian body *ex vivo* with at least one stressor selected from the group consisting of a temperature above or below body temperature, ultraviolet light and an oxidative environment; and [(b)] (c) administering the aliquot of blood treated in step [(a)] (b) to the mammalian body; thereby reducing the rate of or susceptibility to apoptosis or necrosis of tissues and organs.

7. (amended) The process of claim 2 [5] wherein said at least one stressor is ultraviolet light in the UV-C band wavelength.